MAY - 4 2000

510(k) SUMMARY

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K000939.

Submitted by:

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Contact: Robert E. Lovins, PhD
Date Submitted: October 13,1999

Device Identification:

Trade Name: HTF-HEPES Medium

Common Name: Gamete and embryo culture, storage and transfer Medium, Human Tubal Fluid medium

Classification Name: Reproductive Media (21CFR, 886.6180)

Predicate Device:

Notice of Final Rule, 63 FR 48428, Docket number 97N-0335 and 510(k) Reference Number K983586

Description:

HTF-HEPES is a synthetic, defined culture medium intended for use in assisted reproductive technology procedures. It has been formulated to mimic the composition of the fluid found in fallopian tubes as defined by Quinn etal (Quinn P, Kerin JF, Warnes GM: Fertil Steril 1985;44:493-498). HTF-HEPES uses a combined sodium bicarbonate/HEPES ([4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid]) buffering system and is appropriate for those procedures that do not use a carbon dioxide atmosphere.

Intended Use:

HTF-HEPES is intended for the retrieval, culture, transport, storage and transfer of human gametes and embryos.

Design Characteristics:

HTF-HEPES is intended for use as a culture medium, with appropriate protein supplementation, for a variety of assisted reproductive procedures. It has been used for a number of years as a sperm-washing medium. During sperm wash procedures, viable sperm cells are separated from the other constituents of seminal fluid in an effort to concentrate the viable sperm and increase the number of available for fertilization. A culture medium such as HTF-HEPES is used to suspend the semen, the sample is centrifuged to pellet the viable sperm and after the supernatant is decanted, the pellet is resuspended in fresh medium. After a brief incubation period during which the motile sperm "swim up" into the fresh medium, the sperm are aspirated and used for the desired fertilization procedure. HTF-HEPES medium is also used as an oocyte retrieval medium in procedures that flush oocytes from the patient's fallopian tubes. Once the oocyte has been retrieved, it is placed into a culture dish with an appropriate amount of culture medium, and fertilized. After fertilization, the embryo is allowed to develop in an appropriate culture medium until the desired developmental stage is reached. At that time, the embryo is removed from the incubation dish, placed into a suitable amount of HTF-HEPES for transport and implantation into the patient. HTF-HEPES is therefore intended for use as a sperm-washing medium, an oocyte retrieval medium and as a transport and storage medium.

Performance Data:

HTF-HEPES medium is subjected to cytotoxicity testing and sperm motility/hyperactivation analysis. Each lot of HTF-HEPES is also assayed by a mouse embryo assay prior to its release to market. These assays assure that the product is both functional for its intended use, the support of embryonic growth, and that no toxic components are present in the formulation. Modified human tubal fluid media have been used in a variety of clinical settings, for the intended use for a number of years. In that time the product has become the standard media used for the retrieval, growth, storage and transport of human gametes and embryos.

Additional Information:

Mouse embryo testing will be performed as a condition of release for HTF-HEPES medium as well as endotoxin and sterility testing. Results of all release assays will be reported on a lot-specific certificate of analysis and will be indicated on the labeling.

Conclusion:

The conclusion from performance testing, as well as a review of published historical information contained in the professional literature shows that HTF-HEPES is suitable for its intended use and meets the criteria outlined in the Final Rule, 63 FR48428, Docket number 97N-0335.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2000

Robert E. Lovins, Ph.D.
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Re: K000939
HTF-HEPES
Dated: March 22, 2000
Received: March 23, 2000
Regulatory Class: II
21 CFR §884.6180/Procode: 85 MQL

Dear Dr. Lovins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

INDICATIONS FOR USE STATEMENT (Page 1 of 1)

510(k) number: K000939

Device Names: HTF-HEPES Medium

Indications for Use:

HTF-HEPES Medium is intended for use in assisted reproductive technology procedures that involve the manipulation of gametes and embryos. Specifically, HTF-HEPES is intended for use as a sperm processing medium in washing procedures, as an oocyte retrieval medium, for transport of the embryo and as a support medium for implantation of the embryo. HTF-HEPES is intended to simulate the substances found in the human female reproductive system

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000939

Prescription Use X
(per 21 CFR 801.109)